

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA**

TWIN CITIES PIPE TRADES WELFARE FUND,  
individually and on behalf of all others similarly  
situated,

*Plaintiff,*

v.

DR. REDDY'S LABORATORIES, INC., IMPAX  
LABORATORIES, INC., MYLAN INC., MYLAN  
PHARMACEUTICALS INC., PAR  
PHARMACEUTICAL, INC., PAR  
PHARMACEUTICAL COMPANIES, INC., AND  
ZYDUS PHARMACEUTICALS (USA), INC.,

*Defendants.*

Case No. \_\_\_\_\_

**CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

**I. INTRODUCTION**

1. Plaintiff Twin Cities Pipe Trades Fund ("Pipe Trades Fund" or "Plaintiff"), brings this action both individually and on behalf of (a) a national injunctive class of persons or entities in the United States and its territories who purchased, paid and/or provided reimbursement for some or all of the purchase price of generic divalproex sodium extended-release tablets ("divalproex ER") manufactured by Defendants during the period from as early as October 1, 2013, to the present and (b) a damages class of persons or entities who purchased, paid and/or provided reimbursement for some or all of the purchase price of divalproex ER manufactured by Defendants during the period from as early as October 1, 2013, to the present in Minnesota. Defendants are accused of engaging in a conspiracy to fix, maintain, and/or stabilize the prices of divalproex ER and to allocate markets and customers for this product in the United States. All allegations herein are based on information and belief, except for those relating to the Plaintiff.

### **JURISDICTION AND VENUE**

2. Plaintiff brings this action under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive relief and costs of suit, including reasonable attorneys' fees, against Defendants for the injuries sustained by Plaintiff and the members of the Class by reason of the violations of Section 1 of the Sherman Act, 15 U.S.C. § 1, and under the antitrust and common laws of Minnesota for damages and equitable relief.

3. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337, via Section 16 of the Clayton Act, 15 U.S.C. § 26, and supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367.

4. This Court has personal jurisdiction over each Defendant because, *inter alia*, each Defendant: (a) transacted business throughout the United States, including in this District; (b) sold divalproex ER throughout the United States, including in this District; (c) had substantial contacts with the United States, including in this District; and/or (d) was engaged in an illegal scheme and price-fixing and market allocation conspiracy that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District. This Court also has jurisdiction over this matter under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for the proposed class exceeds \$5,000,000 and at least one member of the Damages Class is a citizen of a state different from that of one of Defendants.

5. Venue is proper in this judicial district pursuant to Section 12 of the Clayton Act, 15 U.S.C. §§ 15(a) and 22, and 28 U.S.C. § 1391(b), (c) and (d) because during the Class Period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the affected interstate trade and commerce described below has been

carried out in this District. Venue is also proper in this District because the federal grand jury investigating the pricing of generic drugs is empaneled here and executives of drug companies have been charged for engaging in anticompetitive conduct in this District. Further, Mylan is headquartered within this District and Impax's generics division, Global Pharmaceuticals ("Global"), is located within this District. Therefore, it is likely that acts in furtherance of the alleged conspiracy took place here.

## **II. THE PARTIES**

### **A. Plaintiff**

6. Plaintiff Twin Cities Pipe Trades Welfare Fund is a Taft-Hartley fund authorized pursuant to Section 302(c)(5) of the National Labor Relations Act, with its principal place of business in St. Paul, Minnesota, and an employee welfare benefit plan as defined in Section 3(1) of ERISA. Pipe Trades Fund is the sponsor of a plan of benefits that is the Pipe Trade Services MN Welfare Plan, which provides health benefits, including prescription drug benefits, to approximately 13,700 active participants, retirees, and their spouses and dependents. Pipe Trades Fund purchased and/or provided reimbursement for some or all of the purchase price of generic divalproex ER manufactured by one or more Defendants, other than for re-sale, in Minnesota, during the Class Period, at supra-competitive prices. As a result of the alleged conspiracy, Plaintiff paid and reimbursed more for these products than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets and customers.

### **B. Defendants**

7. Defendant Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's") is a corporation with its principal place of business at 107 College Road East, Princeton, New Jersey, 08540. Dr. Reddy's is a subsidiary of Dr. Reddy's Laboratories Ltd., an Indian company with its principal

place of business located at 8-2-337, Road No. 3, Banjara Hills, Hyderabad Telangana, India, 5000034. Dr. Reddy's manufactures, markets, and sells various generic drugs. During the Class Period, Dr. Reddy's sold generic divalproex ER in the United States.

8. Defendant Impax Laboratories, Inc. ("Impax") is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California, 94544. Impax is a technology-based specialty pharmaceutical company. Impax's generics division is called Global Pharmaceuticals. During the Class Period, Impax manufactured and sold generic divalproex ER in the United States through its Global Pharmaceuticals division.

9. Defendant Mylan Inc. is a Pennsylvania corporation with its principal place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania, 15317.

10. Defendant Mylan Pharmaceuticals Inc. is a West Virginia corporation with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

11. Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. are collectively referred to as "Mylan." Mylan manufactures, markets, and sells branded and generic pharmaceutical products in the United States. During the Class Period, Mylan sold generic divalproex ER in the United States.

12. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York, 10977.

13. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York, 10977.

14. Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are collectively referred to as "Par." Par manufactures, markets, and sells generic pharmaceutical products in the United States. In May 2015, Endo announced that it was acquiring Par for \$8.05

billion. The merger was completed in September 2015. During the Class Period, Par sold generic divalproex ER in the United States.

15. Defendant Zydus Pharmaceuticals (USA) Inc. (“Zydus”) is a New Jersey corporation with its principal place of business at 73 Route 31 N, Pennington, New Jersey, 08534. Zydus is a subsidiary of Zydus Pharmaceuticals Limited, an Indian pharmaceutical company. Zydus manufactures, markets, and sells various generic pharmaceutical products. During the Class Period, Zydus manufactured and sold generic divalproex ER in the United States.

16. Various other persons, firms, corporations and entities not currently named as Defendants in this action have participated as unnamed co-conspirators with Defendants in the violations and conspiracy alleged herein. In order to engage in the offenses charged and violations alleged herein, these co-conspirators have performed acts and made statements in furtherance of the antitrust violations and conspiracies alleged herein.

17. At all relevant times, each Defendant was an agent of each of the Defendants, and in doing the acts alleged herein, was acting within the course and scope of such agency. Each Defendant ratified and/or authorized the wrongful acts of each of the Defendants. Defendants, and each of them, are individually sued as participants and as aiders and abettors in the improper acts and transactions that are the subject of this action.

### **III. INTERSTATE TRADE AND COMMERCE**

18. The business activities of Defendants that are the subject of this action were within the flow of, and substantially affected, interstate trade and commerce.

19. During the Class Period, Defendants sold substantial quantities of generic divalproex ER in a continuous and uninterrupted flow of interstate commerce to customers throughout the United States.

#### IV. FACTUAL ALLEGATIONS

##### A. The Generic Drug Industry

20. The claims in this case arise from a broad conspiracy among manufacturers of generic drugs to fix the prices charged for those drugs in recent years. The conspiracy appears to have been effectuated by direct company-to-company contacts among generic drug manufacturers, as well as joint activities undertaken through trade associations and other communications. The unlawful acts undertaken with respect to generic divalproex ER are a manifestation of that overall conspiracy.

21. According to the FDA's Glossary, a generic drug is "the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use."<sup>1</sup> Once the FDA approves a generic drug as "therapeutically equivalent" to a brand drug, the generic version "can be expected to have equal effect and no difference when substituted for the brand name product." *Id.*

22. Generic drugs are an important part of the healthcare system in the United States, comprising nearly 8 in 10 prescriptions filled.<sup>2</sup> Due to the price differentials between branded and generic drugs, as well as other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute the generic drug when presented with a prescription for the branded drug.

23. The entire purpose of permitting a generic drug industry in the United States was to encourage the manufacture of less expensive, non-branded substitutes for branded prescription drugs that either had no patent exclusivity or for which the patent exclusivity was expiring. In a

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<sup>1</sup> See <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G>.

<sup>2</sup> See <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm>.

January 2012 report, the Government Accountability Office (“GAO”) noted that “[o]n average, the retail price of a generic drug is 75 percent lower than the retail price of a brand-name drug.”<sup>3</sup>

24. The Hatch-Waxman Act, (Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b; 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282)), simplified the regulatory process for bringing generic branded drugs to the public. The Act eliminated the requirement that generic companies file a complex New Drug Application (“NDA”) to obtain U.S. Food and Drug Administration (“FDA”) approval, and eliminated a requirement regarding duplicative clinical trials that had been necessary for a generic drug to obtain approval. In its place, the Act created a system requiring drug companies wishing to bring a generic drug to market to file an Abbreviated New Drug Application (“ANDA”) and allowed generic drug makers to rely on the safety and efficacy data provided by the original NDA holder. Additionally, the Hatch-Waxman Act made other changes related to the time period during which branded drugs would enjoy a period of generic marketing exclusivity.

25. Since passage of the Hatch-Waxman Act, every state has adopted substitution laws requiring or permitting pharmacies to substitute generic-drug equivalents for branded drug prescriptions (unless the prescribing physician specifically orders otherwise by writing “dispense as written” or similar language on the prescription).

26. Entry of generics into the market is intended to increase competition and decrease prices for the benefit of consumers and their overall health. This purpose is made even more urgent given the need for adequate and affordable healthcare. In recent years, however, the

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<sup>3</sup> See GAO-12-371R, *Savings from Generic Drug Use*, <http://www.gao.gov/assets/590/588064.pdf>.

prices of certain commonly prescribed generic drugs have skyrocketed. These dramatic price increases cannot be explained by normal market forces.

27. Generic drugs are exact substitutes for brand-name drugs that have met FDA standards for bioequivalence and pharmaceutical equivalence. To be approved by the FDA by way of an ANDA, a generic drug product must contain the same active ingredient(s) in the same dosage form and in the same strength, and are bioequivalent to the reference listed drug (i.e., the original brand-name version of the drug approved by FDA through an NDA). Under FDA rules, products classified as equivalent can be substituted with the expectation that the substituted product will have the same clinical effect and safety profile as the prescribed product.

28. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug will not infringe the patent of the drug of which it is the generic (called a “Paragraph IV Certification”). A Paragraph IV Certification states “that such patent [for the brand-name drug] is invalid or will not be infringed by the [generic manufacturer’s proposed product].”

29. As an incentive to spur generic companies to provide alternatives to branded drugs, the first generic manufacturer to file a substantially complete ANDA containing a Paragraph IV Certification is permitted to market its generic drug free from competing generic manufacturers for a set period of time. Often the first generic in the market enters at a price well below the branded drug and quickly takes a large market share from the branded drug. As more generics enter the market, as Professor Stephen W. Schondelmeyer explains,<sup>4</sup> their prices “continue to fall compared to the brand price, and their combined share of the market for the

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<sup>4</sup> Professor Stephen W. Schondelmeyer (BS Pharm., MA Pub Adm., Pharm.D., Ph.D., PAPhA) is head of the Department of Pharmaceutical Care and Health Systems at the University of Minnesota, where he holds the Century Mortar Club Endowed Chair in Pharmaceutical Management and Economics.



molecule, relative to the brand name equivalent, usually continues to grow.”<sup>5</sup> Professor Schondelmeyer also states:

The Congressional Budget Office has credited the Hatch-Waxman Act and, importantly, the process for easy and routine A-rated generic substitution by pharmacists with providing meaningful economic competition from generic drugs, and with achieving billions of dollars of savings for drug purchasers such as consumers and employers.

30. In remarks to Congress in November 2014, Professor Schondelmeyer noted the trend of generic-drug prices rising, and rising at a rate far outpacing the rate of general inflation – a rate of 12.9% compared to 1.5%. He also explained that “[t]he average annual retail price increase for brand name prescription drug products in 2013 (12.9 percent) was more than two times higher than the average annual brand name drug price increase in 2006 (5.7 percent).”<sup>6</sup>

31. Professor Schondelmeyer has explained that “the market for pharmaceuticals is out of balance. Prices are not transparent. Without actual price data, it is not possible to make true value-based decisions. Certainly price is not the only issue in a value-based decision, but price is always an issue in value-based decisions. In many ways the pharmaceutical market is very asymmetric – the seller knows a lot more about the product than does the buyer.”<sup>7</sup>

## **V. GOVERNMENT INVESTIGATIONS INTO GENERIC DRUG PRICING**

### **A. Congressional Investigations into Generic Drug Pricing**

32. Several generic drug companies have been the target of governmental investigations into anticompetitive generic drug pricing. The DOJ’s Antitrust Division has

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<sup>5</sup> See *Why Are Some Generic Drugs Skyrocketing in Price?*: Hearing before the S. Comm. on Health, Education, Labor and Pensions, 113th Cong. (Nov. 20, 2014) (Statement of Stephen W. Schondelmeyer).

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

launched investigations, and Congress has taken an interest as well, holding hearings and calling for an investigation.

33. In a January 8, 2014 letter to members of key committees of the United States House of Representatives and United States Senate, Douglas P. Hoey, chief executive officer of the National Community Pharmacists' Association, asked Congress to conduct an investigation of generic drug price increases.<sup>8</sup>

34. On October 2, 2014, Representative Elijah E. Cummings, the Ranking Member of the House Committee on Oversight and Government Reform, and Senator Bernard Sanders, Chairman of the Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions, sent letters to 14 drug manufacturers—including Defendants Dr. Reddy's Impax, Mylan, Par, and Zydus—"requesting information about the escalating prices of generic drugs used to treat everything from common medical conditions to life-threatening illnesses."<sup>9</sup> The letters specifically sought information about divalproex ER from Dr. Reddy's, Mylan, Par, and Zydus.

35. "It is unacceptable that Americans pay, by far, the highest prices in the world for prescription drugs," Sen. Sanders said in a news release. "Generic drugs were meant to help make medications affordable for the millions of Americans who rely on prescriptions to manage their health needs. We've got to get to the bottom of these enormous price increases."

36. "When you see how much the prices of these drugs have increased just over the past year, it's staggering, and we want to know why," Rep. Cummings stated in the same news release. "I am very pleased that Chairman Sanders has joined me in this bicameral investigation

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<sup>8</sup> See <https://www.ncpanet.org/pdf/leg/jan14/letter-generic-spikes.pdf>.

<sup>9</sup> Ranking Members Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs, <http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price-increases?inline=file>.

because in some cases these outrageous price hikes are preventing patients from getting the drugs they need.”

37. These letters, which in addition to being delivered Defendants, were also sent to the heads of Actavis, Apotex, Teva, Endo Pharmaceuticals plc, Heritage Pharmaceuticals Inc., and Marathon Pharmaceuticals, LLC – sought information about the pricing of many generic drugs, including divalproex ER, pravastatin, digoxin, doxycycline, albuterol sulfate, glycopyrrolate, neostigmine methylsulfate, benazepril/hydrochlorothiazide, Isuprel® (isoproterenol hydrochloride), and Nitropress® (nitroprusside). The congressmen cited a survey finding that pharmacists across the U.S. ““have seen huge upswings in generic drug prices that are hurting patients”” resulting in patients “declining their medication due to increased co-pays” and having a ““very significant”” impact on pharmacists’ ability to continue serving patients. The study, conducted for the National Community Pharmacists Association, also found some patients refused to fill needed prescriptions because of rising prices.<sup>10</sup>

38. The table, published by Sen. Sanders and Rep. Cummings, in connection with their letters, demonstrating the massive price increases that divalproex ER has experienced over the past several years:

Drug	Use	Average Market Price Oct. 2013	Average Market Price April 2014	Average Percentage Increase
Divalproex Sodium ER (bottle of 80, 500 mg tablets ER 24H)	used to prevent migraines and treat certain types of seizures	\$31	\$234	736%

39. On November 20, 2014, the Subcommittee on Primary Health and Aging of the Senate Committee on Health, Education, Labor and Pensions held a hearing entitled “Why Are

<sup>10</sup> Congress Investigating Why Generic Drug Prices Are Skyrocketing, <http://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing>.

Some Generic Drugs Skyrocketing In Price?” Various witnesses discussed the price hikes for generic drugs. Executives of generic-drug makers were invited to testify, but declined to appear.<sup>11</sup>

40. In addition to sending letters to the generic drug manufacturers listed above, Senator Sanders and Representative Cummings wrote a joint letter to Sylvia Burwell, the Department of Health and Human Services Secretary, stating, “The federal government must act immediately and aggressively to address the increasing costs of these drugs.”<sup>12</sup>

41. On February 24, 2015, Senator Sanders and Representative Cummings wrote to Daniel R. Levinson, the Inspector General of the Department of Health and Human Services, imploring the department to “examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare and Medicaid programs.”<sup>13</sup>

42. On April 13, 2015, Inspector General Levinson responded to Senator Sanders and Representative Cummings’s letter, stating that his office planned “to update our previous review of generic drug price increases under the Medicaid drug rebate program.”<sup>14</sup>

43. Subsequent congressional hearings concerning the dramatic rise of generic drug prices were held in December 2015 and February 2016. At the U.S. Senate Special Committee on Aging’s December 9, 2015 hearing, Erin D. Fox, PharmD Director of the Drug Information

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<sup>11</sup> See <http://www.sanders.senate.gov/newsroom/press-releases/drugmakers-mum-on-huge-price-hikes>.

<sup>12</sup> Congressional Panel to Probe Generic Drug Price Hikes (Nov. 11, 2014), <http://www.sanders.senate.gov/newsroom/press-releases/congressional-panel-to-probe-generic-drug-price-hikes>.

<sup>13</sup> Letter from Hon. Bernard Sanders and Elijah Cummings to Hon. Daniel Levinson (Feb. 24, 2015), <http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file>.

<sup>14</sup> Letter from Hon. Daniel Levinson to Hon. Bernard Sanders (Apr. 13, 2015), <http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file>.

Service of the University of Utah, noted the deleterious effect these drug prices have had on patient access and healthcare, stating, “When medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage.”<sup>15</sup>

#### **B. Federal and State Antitrust Investigations into Defendants’ Generic Drug Pricing**

44. Generic pricing patterns also captured the attention of federal and state enforcement authorities in the United States. In 2014, the Antitrust Division of the United States Department of Justice (“DOJ”) began a criminal investigation of this conspiracy. Multiple generic drug companies have received subpoenas or requests for information concerning their pricing of generic drugs, as well as their communications with their competitors for those drugs in connection with both federal or state antitrust probes, including Defendants Impax, Par, Mylan, Dr. Reddy’s, and Zydus. Generic drug manufacturers Lannett, Activis, Sun, Mayne Pharme Ltd., Teva, and Taro have also received subpoenas from the DOJ and/or CTAG.

45. Initial reports suggest that, at the beginning, the probes were focused on two generic drugs: digoxin and doxycycline. Recent news reports have confirmed the DOJ’s investigation is significantly broader and encompasses as many as a dozen generic drug manufacturers and is examining a conspiracy to fix, raise, maintain and stabilize the prices of as many as two dozen generic drugs, including divalproex ER. Moreover, these reports suggest that

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<sup>15</sup> Statement of Erin R. Fox, PharmD Director, Drug Information Service, Hearing on “Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines” (Dec. 9, 2015), at 7, [http://www.aging.senate.gov/hearings/sudden-price-spikes-in-off-patent-drugs\\_perspectives-from-the-front-lines?](http://www.aging.senate.gov/hearings/sudden-price-spikes-in-off-patent-drugs_perspectives-from-the-front-lines?).

a leniency applicant came forward during the summer of 2016 and is working with the DOJ in its ongoing investigation.<sup>16</sup>

46. A federal grand jury investigating the matter is empaneled in the Eastern District of Pennsylvania. The DOJ's two year-old investigation has progressed to such a degree that the first criminal charges were filed against two executives of generic drug manufacturer Heritage Pharmaceuticals, Inc. on December 14, 2016 for their conduct related to doxycycline hyclate (an antibiotic) and glyburide (a treatment for diabetes).<sup>17</sup>

47. These investigations could result in the imposition of substantial fines and criminal pleas for generic manufacturers, and jail time for company executives. Some analysts have estimated that Mylan could face liability between \$380 million and \$770 million and that the DOJ could impose industry-wide fines in excess of \$1 billion.<sup>18</sup>

48. In addition to the DOJ's investigation, the Connecticut Attorney General's Office ("CTAG"), as part of twenty-state working group of state attorneys general, is conducting a probe the same conduct. On December 15, 2016, the CTAG and nineteen other states filed a civil action in the United States District Court for the District of Connecticut against Defendant Mylan and generic drug manufacturers Aurobindo Pharma USA, Inc., Citron Pharma, LLC,

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<sup>16</sup> Leah Nylen & Josh Sisco, *Comment: Generic drug investigation started small before ballooning to dozen companies* (Nov. 4, 2016).

<sup>17</sup> Tom Schoenberg, David McLaughlin and Sophia Pearson, *U.S. Files First Charges in Generic Drug Price-Fixing Probe* (Dec. 14, 2016), [https://www.bloomberglaw.com/product/blaw/exp\\_blp/ewogICAgImN0eHQiOiAiRE9DIiwKICAgICJpZCI6ICJPSTZQNEo2SkIKVjg/cmVzb3VyY2VfaWQ9Mzk3M2JIMGEyZjYyZTVmODRhMjVhNWl3OWU5NDEzMjYiLAogICAgInNpZyI6ICJ3RU9LOWNcL3pNQ1dcL0pyc3RRQnBxU2E4RFU3RT0iLAogICAgInRpbWUiOiAiMTQ4MTc1MTgxMiIsCiAgICAidXVpZCI6ICJnekY0c1FYTWI1FaHhmSE95Vm9GVnJRPT1ldGIdeUVnMGdYU0Nodm9URDNDN2hRPT0iLAogICAgInYiOiAiMSIKfQo=?emc=BLAW:120052461:0](https://www.bloomberglaw.com/product/blaw/exp_blp/ewogICAgImN0eHQiOiAiRE9DIiwKICAgICJpZCI6ICJPSTZQNEo2SkIKVjg/cmVzb3VyY2VfaWQ9Mzk3M2JIMGEyZjYyZTVmODRhMjVhNWl3OWU5NDEzMjYiLAogICAgInNpZyI6ICJ3RU9LOWNcL3pNQ1dcL0pyc3RRQnBxU2E4RFU3RT0iLAogICAgInRpbWUiOiAiMTQ4MTc1MTgxMiIsCiAgICAidXVpZCI6ICJnekY0c1FYTWI1FaHhmSE95Vm9GVnJRPT1ldGIdeUVnMGdYU0Nodm9URDNDN2hRPT0iLAogICAgInYiOiAiMSIKfQo=?emc=BLAW:120052461:0).

<sup>18</sup> Eric Saonowsky, *DOJ's price-fixing investigation could lead to sizable liabilities, analyst says*, FiercePharma (Nov. 10, 2016), <http://www.fiercepharma.com/pharma/doj-s-price-fixing-investigation-could-lead-to-sizable-liabilities-analyst-says>.

Heritage Pharmaceuticals, Inc., Mayne Pharma (USA), Inc., and Teva Pharmaceuticals USA, Inc. The suit alleged that Mylan and other generic drug manufacturers engaged in a “wide-ranging series of conspiracies implicating numerous different drugs and competitors, which will be acted upon at the appropriate time” and specifically alleged that generic drug manufacturers, including Mylan, conspired to allocate market share and artificially inflate and maintain prices in the markets for doxycycline hyclate delayed release and glyburide.<sup>19</sup>

49. In July 2014, Impax disclosed that it received a subpoena from the CTAG concerning Impax’s sales of generic digoxin and whether it agreed with others to fix prices or allocate customers or territories. In November 2014, Impax disclosed that one of its sales representatives received a federal grand jury subpoena requesting testimony and documents about “any communication or correspondence with any competitor about the sale of generic drugs.”<sup>20</sup> The scope of the subpoenas was not limited to a particular drug or a particular timeframe.

50. On March 13, 2015, Impax further disclosed that “the Company received a grand jury subpoena from the Justice Department requesting the production of information and documents regarding the sales, marketing, and pricing of certain generic prescription medications. In particular the Justice Department’s investigation currently focuses on four generic medications: digoxin, terbutaline sulfate tablets, prilocaine/lidocaine cream, and calcipotriene topical solution.”<sup>21</sup>

51. Similarly, in an SEC Form 10-K for 2014, Par disclosed that it had received a subpoena from DOJ “requesting documents related to communications with competitors

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<sup>19</sup> *Connecticut v. Aurobindo Pharma USA, Inc. et al.*, Civ. No. 3:16-cv-02056-VLB (D. Conn. Dec. 15, 2016).

<sup>20</sup> Impax SEC Form 8-K (Nov. 6, 2014).

<sup>21</sup> Impax SEC 2015 Form 10-K, at F-53.

regarding our authorized generic version of Covis's Lanoxin<sup>®</sup> (digoxin) oral tablets and our generic doxycycline products."<sup>22</sup> Moreover, in that same filing Par revealed that the CTAG served a subpoena on Par on August 6, 2014 "requesting documents related to our agreement with Covis Pharma S.a.r.l. to distribute an authorized generic version of Covis's Lanoxin<sup>®</sup> (digoxin) oral tablets."<sup>23</sup> Par stated that it completed its response on October 28, 2014.

52. Its August 2016 SEC Form 6-K, Dr. Reddy's disclosed that in November 2014 it had received a Civil Investigated Demand from the Office of the Attorney General for the State of Texas requesting information about the sales and pricing of certain products and a subpoena *duces tecum* from the Office of the Attorney General for the State of California to produce records and documents regarding the pricing of fifteen products.<sup>24</sup>

53. Similarly, in its August 2016 6-K, Dr. Reddy's disclosed that it had received a subpoena from the DOJ on July 6, 2016, "seeking information relating to the marketing, pricing and sale of certain . . . generic products and any communications with competitors about such products."<sup>25</sup> In that same filing, Dr. Reddy's disclosed that it had received a subpoena from the CTAG concerning the same matters.

54. Mylan similarly disclosed in a 2016 SEC filing that it received a subpoena from the DOJ in December 2015 "seeking information relating to the marketing, pricing, and sale of our generic Doxycycline products and any communications with competitors about such products."<sup>26</sup>

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<sup>22</sup> Par Pharmaceuticals Companies, Inc. SEC 2014 Form 10-K, at 37.

<sup>23</sup> *Id.*

<sup>24</sup> Dr. Reddy's SEC Form 6-K (Aug. 11, 2016).

<sup>25</sup> *Id.*

<sup>26</sup> Mylan SEC 2015 Form 10-K, at 160.



55. In December 2015, Mylan received a similar subpoena from the CTAG, seeking “information relating to the marketing, pricing and sale of certain of the Company’s generic products (including Doxycycline) and communications with competitors about such products.”<sup>27</sup>

56. In its 2016 SEC filing, Mylan also disclosed that DOJ issued a subpoena in September 2016 to Mylan and certain employees and senior management “seeking additional information relating to the marketing, pricing and sale of our generic Cidofovir, Glipizide-metformin, Propranolol and Verapamil products and any communications with competitors about such products.”<sup>28</sup> Significantly, Mylan also disclosed that “[r]elated search warrants also were executed” in connection with DOJ’s investigation.<sup>29</sup> The issuance of warrants represents a significant escalation of the DOJ’s investigation because to obtain a warrant, the government must demonstrate “probable cause.”

57. Although Zydus is not publicly traded in the United States and thus not subject to reporting requirements under federal securities laws, recent press reports have stated the Zydus is also a target of the DOJ’s sweeping investigation.<sup>30</sup> According to one article, Zydus is being investigated in connection with its marketing and sale of divalproex ER.<sup>31</sup>

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<sup>27</sup> *Id.*

<sup>28</sup> Mylan SEC Form 10-Q, at F-106.

<sup>29</sup> *Id.*

<sup>30</sup> Rupali Mukherjeel, *US polls, pricing pressure may hit Indian pharma cos*, The Times of India, (Nov. 8, 2016), <http://timesofindia.indiatimes.com/business/india-business/US-polls-pricing-pressure-may-hit-Indian-pharma-cos/articleshow/55301060.cms>.

<sup>31</sup> *Hillary win may pose pricing challenges for pharma cos: Report*, F. World (Nov. 7, 2016), <http://www.firstpost.com/world/hillary-win-may-pose-pricing-challenges-for-pharma-cos-report-3093544.html>.

## **VI. THE DIVALPROEX ER MARKET AND PRICING**

58. Divalproex ER is a commonly prescribed anticonvulsant indicated for the treatment of migraines and seizures. Divalproex ER is derived from valproate, which has been known since the late 19th century and has been used as medicine since the 1960s. Valproate has been designated an essential medicine by the World Health Organization.

59. AbbVie manufactures and sells a branded version of divalproex ER under the name Depakote ER®. AbbVie's predecessor-in-interest, Abbott Laboratories, submitted NDA 21-168 for the approval of Depakote ER on September 30, 1999. The FDA approved Depakote ER on August 4, 2000, and Abbott Laboratories began selling the drug soon thereafter. Depakote ER was an extremely successful drug for AbbVie, generating over \$900 million in sales.

60. Drug market analysts have noted that divalproex ER is a "low competition" market. Generic drug manufacturers that currently market generic versions of divalproex ER in the United States are Mylan, Par, Dr. Reddy's, Impax, and Zydus. Mylan and Par are by far the dominant players in the divalproex ER market. Together they have well over 50% of the divalproex ER market. Dr. Reddy's, Impax, and Zydus also have significant shares of the generic divalproex ER market.

61. Generic versions of divalproex ER has been on the market for years and, for most of that time, has been priced significantly lower than its branded counterpart – in many instances priced at less than a dollar per tablet. This is because the presence of generic drugs usually results in vigorous price competition, benefiting consumers and third-party payors through lower prices.

- a. Dr. Reddy's received approval to market generic versions of divalproex ER in March 2012.
- b. Impax received approval to market generic versions of divalproex ER in May

2009.

- c. Mylan received approval to market generic versions of divalproex ER in January 2009.
- d. Par's predecessor-in-interest, Anchen Pharmaceuticals, received approval to market generic versions of divalproex ER in March 2009.
- e. Zydus received approval to market generic versions of divalproex ER in February 2009.

62. Recently, generic divalproex ER has experienced unprecedented price increases. Between the fourth quarter of 2013 and the beginning of the second quarter of 2014, the price of divalproex ER has increased over 500%. The U.S. Government Accountability Office ("GAO") noted that divalproex ER had experienced "extraordinary price increases" between 2010 and 2015.<sup>32</sup>

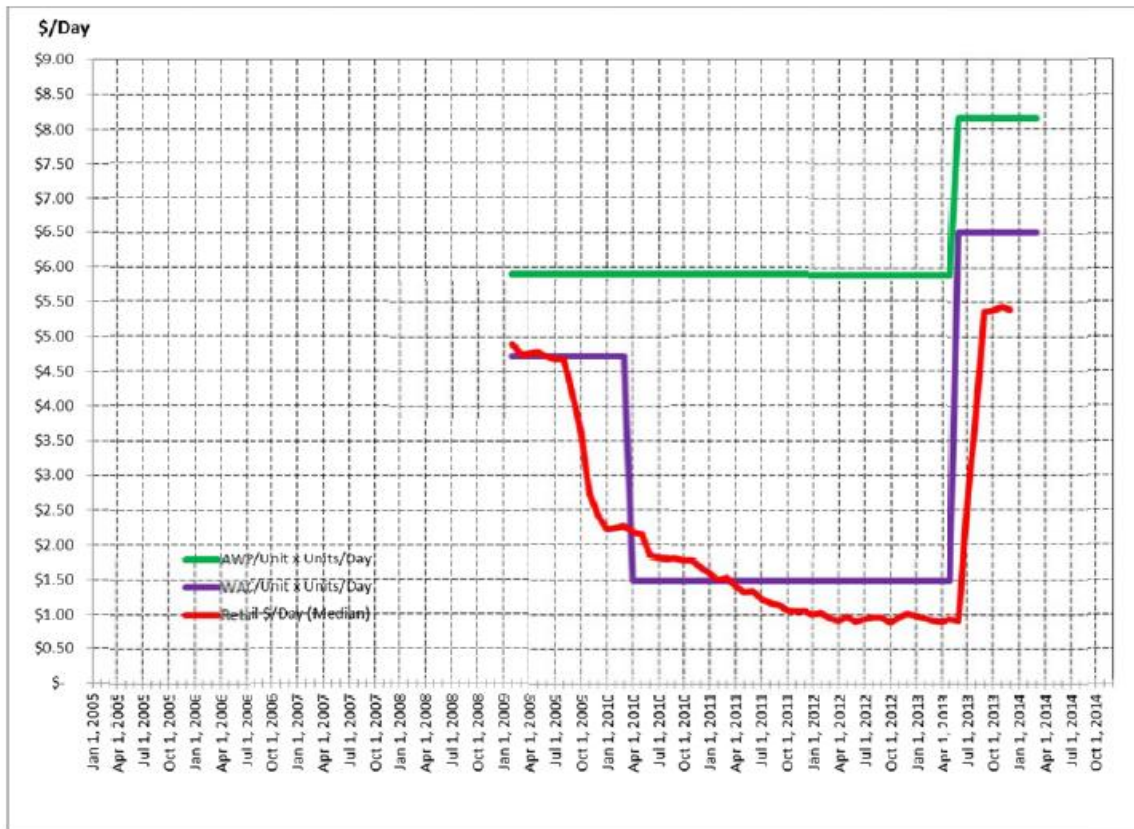
63. The tremendous increase in divalproex ER pricing occurred between July 2013 and September 2013 when the median retail price of divalproex ER increased from less than \$1 per day to almost \$5.50 per day.<sup>33</sup>

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<sup>32</sup> See GAO, *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases*, No. 16-706, App'x III (Aug. 2016), <http://www.gao.gov/assets/680/679022.pdf>

<sup>33</sup> See *Why Are Some Generic Drugs Skyrocketing in Price?*: Hearing before the S. Comm. on Health, Education, Labor and Pensions, 113th Cong. (Nov. 20, 2014) (Statement of Stephen W. Schondelmeyer).

**Figure 13. Divalproex Sodium 500 mg Tablet ER 24 Hr (Mylan) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)**



The terms “AWP” and “WAC” in this chart refer, respectively, to “Average Wholesale Price and “Wholesale Acquisition Price.” Both prices are referred to by Dr. Schondelmeyer as benchmark prices.<sup>34</sup>

64. The chart reflects only a portion of the price hikes for divalproex ER. Between October 2013 and April 2014, prices of an 80 count bottle of divalproex ER increased over seven hundred percent from \$31 to \$234.<sup>35</sup>

<sup>34</sup> <http://www.help.senate.gov/imo/media/doc/Schondelmeyer.pdf>.

<sup>35</sup> Ranking Member Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs (Chart associated with investigation).

Drug	SKU	Average Market Price October 2013	Average Market Price April 2014	Cost Increase	Average Percentage Increase
Divalproex Sodium ER	bottle of 100, 250mg, tablets ER 24H	\$30	\$179	\$150	566%
Divalproex Sodium ER	bottle of 100, 500mg, tablets ER 24H	\$43	\$351	\$308	667%
Divalproex Sodium ER	bottle of 300, 500mg, tablets ER 24H	\$145	\$880	\$735	570%
Divalproex Sodium ER	bottle of 80, 500mg, tablets ER 24H	\$31	\$235	\$204	736%

36

65. These price increases are the result of a conspiracy among Defendants wherein Defendants agreed to raise the prices of generic divalproex ER sold to consumers in the United States.

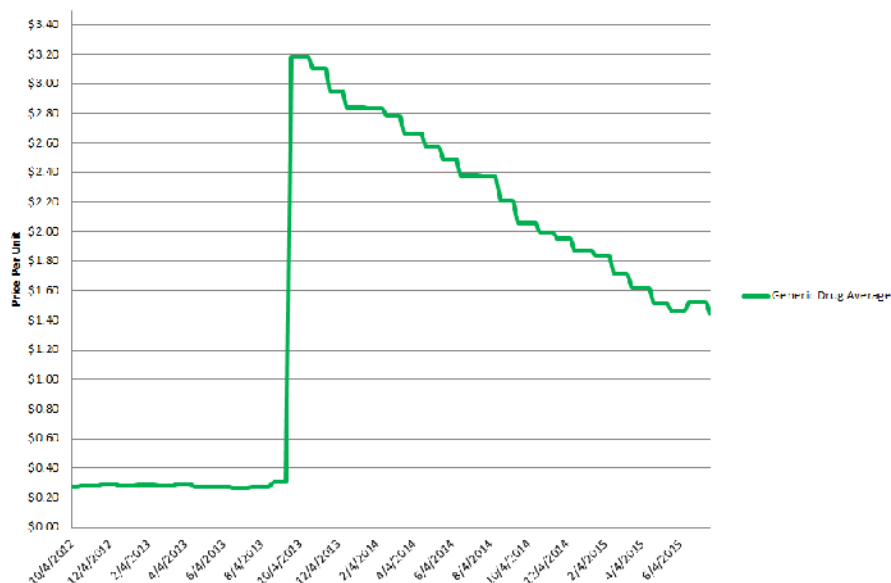
66. Defendants' conspiracy enabled them to raise and maintain supracompetitive prices of divalproex ER in the United States.

67. Defendants' divalproex ER pricing cannot be explained by normal market forces. Demand for divalproex ER has not materially changed between 2010 and the present. One theoretical reason prices might rise would be a supply disruption or shortage. However, federal law requires drug manufacturers to report potential drug shortages to the FDA, the reasons for the potential shortage, and the expected duration of the shortage.<sup>37</sup> No such disruption or shortage was reported by Defendants with respect to divalproex ER in the crucial mid-2013 period. The FDA reported no divalproex ER shortages.

68. Price hikes for divalproex ER were generally industry-wide. The chart below shows the average price per unit (tablet) of generic divalproex ER between October 2012 and July 2015:

<sup>36</sup> Sanders letter to Dr. Reddy's (Oct. 2, 2014).

<sup>37</sup> See <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm#q>.

**Divalproex ER 500 mg**

69. The NADAC data show that prices for generic divalproex ER 500 mg increased **over 920%**, from an average market price of \$0.31 per tablet as of September 12, 2013 to \$3.18 per tablet as of September 19, 2013.

70. Further, although divalproex ER prices have eroded somewhat, they still remain substantially above their pre-September 2013 prices. Defendants' coordinated pricing has deprived, and continues to deprive, Plaintiff and members of the Classes the benefits of free and open competition – namely, lower prices for generic versions of divalproex ER. As a result, Plaintiff and members of the Classes have paid and continue to pay non-competitive prices for generic divalproex ER.

**A. Defendants' Conspiratorial Conduct to Fix Prices and Allocate Customers and Markets for Generic Divalproex ER**

71. Plaintiff alleges that during the Class Period, Defendants conspired, combined and contracted to fix, raise, inflate, maintain, and stabilize prices at which generic divalproex ER would be sold and to allocate the divalproex ER market. As a result of Defendants' unlawful conduct, Plaintiff and the other members of the proposed Classes paid artificially inflated prices

that exceeded the amount they would have paid if a competitive market had determined prices for generic divalproex ER.

72. In formulating and effectuating their conspiracy, Defendants engaged in numerous anticompetitive activities, including, among other things:

- a. Attending joint meetings or otherwise engaging in joint discussions in the United States by telephone, facsimile, and electronic mail regarding the sale of divalproex ER;
- b. Agreeing to charge prices for divalproex ER at specified levels, and otherwise fix, increase, maintain, and stabilize the prices and supply of divalproex ER sold to purchasers in the United States;
- c. Selling divalproex ER to customers in the United States at collusive and non-competitive prices pursuant to the agreement reached;
- d. Accepting payments for divalproex ER sold in the United States at collusive and non-competitive prices;
- e. Communicating with one another to discuss the prices, customers, markets, supply and manufacturing issues, and price levels of divalproex ER sold in the United States;
- f. Authorizing or consenting to the participation of employees in the conspiracy; and
- g. Concealing the conspiracy and conspiratorial contacts through various means.

73. The purpose of these secret, conspiratorial meetings, discussions, and communications was to ensure that all Defendants agreed to participate in, implement, and maintain an unlawful price-fixing and market and customer allocation scheme.

74. As a result of Defendants’ unlawful agreement to restrain trade, Plaintiff and members of the Classes were injured because they paid, and continue to pay, supracompetitive prices for divalproex ER sold in the United States during the period October 1, 2013 through the present.

75. These price hikes were not the result of competitive market forces; instead, they were the result of Defendants’ conspiracy to fix, raise, maintain, and stabilize the prices of, as well as allocate customers and markets for, divalproex ER.

76. Defendants orchestrated their conspiracy through secret communications and meetings, both in private and at public events, such as trade association meetings held by the Generic Pharmaceutical Association (“GPhA”), among others. Trade association meetings, including those sponsored by GPhA, provided divalproex ER manufacturers with the opportunity to meet and agree to fix divalproex ER prices, as well as allocate markets. Mylan and Par met with their fellow divalproex ER producers, including Dr. Reddy’s, Impax, and Zydus, and agreed to raise the prices of divalproex ER sold by them, as well as allocate markets. As a result of the agreement, Mylan and Par raised their prices whenever Dr. Reddy’s, Impax, and Zydus raised theirs – and vice versa.

77. Oligopolistic conditions – e.g., low numbers of competitors and barriers to entry in the market for divalproex – facilitated Defendants’ anticompetitive actions and have allowed them to sustain their unlawful supracompetitive pricing to the present.

#### **B. Trade Associations Facilitated Defendants’ Scheme**

78. The conspiracy over divalproex ER was likely carried out, at least, using trade organizations. According to Policy and Regulatory Report, a news service focused on competition law, a source given inside information by a prosecutor involved in the government’s



investigation said DOJ is closely examining trade associations “as having been one potential avenue for facilitating the collusion between salespeople at different generic producers.”

79. GPhA is the nation’s leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. GPhA was founded in 2000, following the merger of three industry trade organizations: the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

80. GPhA describes itself as “the nation’s leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry.” GPhA gives the generics industry near limitless opportunities to collude under the guise of speaking with a stronger, unified voice before federal and state lawmakers, regulatory policymakers, and international agencies.

81. Current “Regular Members” of the GPhA include Defendants Dr. Reddy’s, Impax, Mylan, Par, and Zydus. Regular Members are entities whose primary U.S. business derives the majority of its revenues from sales of (1) finished dose drugs approved via ANDAs; (2) products sold as authorized generic drugs; (3) biosimilar products; or (4) DESI products.

82. Several of Defendants’ high-ranking officers also serve on GPhA’s Board of Directors, including: Dr. Reddy’s Alok Sonig, Impax’s Marcy Macdonald, Mylan’s Heather Bresch, Par’s Tony Pera, and Zydus’ Joseph Renner. Ms. Bresch serves as the GPhA’s current Chairperson.

83. Representatives from Defendants attended meetings held by GPhA. The following table lists some of the GPhA meetings attended by Defendants' employees (other generic drug manufacturers attended as well):

Meeting	Meeting Date and Location	Attendees
2012 GPhA Annual Meeting	February 22-24, 2012, Orlando, Florida	Mylan, Par
2012 GPhA Fall Technical Conference	October 1- 3, 2012, Bethesda, Maryland	Impax, Mylan, Dr. Reddy's, Par, Zydus
2013 GPhA Annual Meeting	February 20-22, 2013, Orlando, Florida	Impax, Mylan, Par, Dr. Reddy's, Zydus
2013 GPhA CMC Workshop	June 4-5, 2013, Bethesda, Maryland	Dr. Reddy's, Impax, Par, Zydus
2013 GPhA Fall Technical Conference	October 28 -30, 2013, Bethesda, Maryland	Impax, Mylan, Par, Dr. Reddy's, Zydus
2014 GPhA Annual Meeting	February 19-21, 2014, Orlando, Florida	Impax, Mylan, Par, Dr. Reddy's, Zydus
2014 GPhA CMC Workshop	June 3-4, 2014	Dr. Reddy's, Impax, Par, Zydus

84. Defendants also routinely gathered at non-GPhA sponsored events. For example, Defendants' representatives attended the annual JP Morgan Healthcare Conferences in 2012 and 2013, as did representatives of other generic drug manufacturers:

Meeting	Meeting Date and Location	Attendees
30 <sup>th</sup> Annual JP Morgan Healthcare Conference	January 20 12, San Francisco, California	Impax, Mylan, Par
31 <sup>st</sup> Annual JP Morgan Healthcare Conference	January 7- 10, 2013, San Francisco, California	Impax, Mylan, Par

85. Upon information and belief, Defendants' employees discussed their anticompetitive scheme to raise, maintain, and stabilize the prices of divalproex ER, as well as other drugs, and how to allocate markets and customers, at these meetings, among others.

## **VII. GENERIC MARKET FOR DIVALPROEX ER IS SUSCEPTIBLE TO A PRICE FIXING CONSPIRACY**

### **A. Factors Supporting the Existence of a Conspiracy in the Divalproex ER Market**

86. The structure and other characteristics of the divalproex ER market make it conducive to collusion and price-fixing. Specifically, during the Class Period, the divalproex ER market exhibited: (1) high barriers to entry; (2) inelasticity of demand; (3) a high degree of commoditization; (4) a high degree of concentration; (5) substantial manufacturer overlap; (6) competitors acting against their economic self-interest; and (7) opportunities to conspire.

#### **1. There Are High Barriers to Entry in the Generic Divalproex ER Market**

87. Supracompetitive pricing in a market normally attracts additional competitors, who want to avail themselves of the high levels of profitability that are available. However, the presence of significant barriers to entry makes this more difficult and helps facilitate the operation of a cartel.

88. Even though divalproex ER is not protected by any patents, the divalproex ER market nonetheless has high barriers to entry. Here, there are significant capital requirements, high manufacturing costs, and regulatory and intellectual-property barriers to entry into the divalproex ER market. ANDAs alone, which are necessary to bring a new generic drug to market, take an average of 36 months to be approved by the FDA. This process can take even longer if the FDA requires Tier 1 and 2 amendments. Any generic drug manufacturer seeking to enter the divalproex ER market must file an ANDA and receive FDA approval.

89. Further, regulatory hurdles are not only time consuming, but they are also expensive. Any generic drug manufacturer seeking to enter the divalproex ER market must file an ANDA and receive FDA approval. To file an ANDA, the generic manufacturer must show that the generic product is bioequivalent to its branded counterpart and invest considerable resources in the development of production lines capable of making the drug. Historically, the cost of filing an ANDA is about \$1 million, and new estimates suggest that the cost of filing could reach \$5 to \$15 million for a paragraph IV filing.<sup>38</sup> A generic manufacturer's production facilities must also meet CGMP standards, which increase the costs of production.

90. Moreover, a generic manufacturer that cannot produce the Active Pharmaceutical Ingredient ("API") for divalproex ER must have a reliable and affordable source of API for these products.

91. Prospective generic manufacturers must also be able to satisfy FDA regulations and guidance governing bioequivalence and bioavailability of their divalproex ER products. This requires showing that the proposed generic divalproex ER products have, among other things, the same therapeutic qualities and absorption profiles as their branded counterparts.

92. The failure to meet all FDA requirements concerning manufacturing, testing, and labeling of divalproex ER will result in the FDA delaying (or denying) approval of an ANDA. These delays can last for months or even years.

93. Even if a non-conspiring generic manufacturer were to see an opportunity to compete on price regarding divalproex ER, due to the fact that the FDA's review of ANDAs is significantly "backlogged," any potential entrant would necessarily be delayed for years.<sup>39</sup>

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<sup>38</sup> Testimony of Dr. Scott Gottlieb, Hearing on "Why Are Some Generic Drugs Skyrocketing in Price?" (Nov. 20, 2014), at 7.

<sup>39</sup> *Id* at 7.

Indeed, the FDA has stated that as of fiscal year 2015, ANDA approvals can take 40 months or more.<sup>40</sup>

## 2. Inelasticity of Demand for Divalproex ER and Lack of Substitutes

94. Price elasticity of demand is defined as the relationship between a change in the quantity demanded for a product or service, and a change in price for the same product. It measures the impact of a price change on the subsequent demand for a product. The basic necessities of life—food, water, and shelter—are examples of goods that experience nearly perfectly “inelastic” demand at or near the minimums necessary to sustain life. For a cartel to profit from raising prices above competitive levels, demand for the product must be sufficiently inelastic such that any loss in sales will be more than offset by increases in revenue on those sales that are made. Otherwise, increased prices would result in declining revenues and profits. Demand is considered inelastic if an increase in price yields only a small decrease in quantity sold.

95. Divalproex ER is a critical drug for millions of people suffering from migraines and seizures. Other anticonvulsants are not reasonable substitutes because of the therapeutic differences between divalproex ER and other anticonvulsants. For example, gabapentin and topiramate have different pharmacokinetic profiles when compared to valproate, from which divalproex ER is derived. As a result, these compounds are not considered therapeutically equivalent and would not be substituted for divalproex ER at the pharmacy level. For that reason, patients must purchase it at whatever price the Defendants set. As such, demand for

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<sup>40</sup> GOA, *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases*, No. 16-706, at 26 (Aug. 2016), <http://www.gao.gov/assets/680/679022.pdf>.

divalproex ER is highly inelastic because it is a unique product for which there is no reasonable substitute.

96. Even within the subclass of valproate derivatives, divalproex ER stands apart. Although valproate derivatives, such as valproic acid, have similar therapeutic properties to divalproex ER, none is an AB-rated equivalent to divalproex ER.

97. Branded divalproex ER does not serve as an economic substitute for generic divalproex ER. This is because branded products generally maintain substantial price premiums over their generic counterparts, making them inapt substitutes even when generic prices soar.

98. Thus, purchasers of generic divalproex ER have been and continue to be held captive to the supracompetitive prices that resulted from Defendants' conspiracy to fix prices and allocate markets and customers.

### **3. Divalproex ER Is a Highly-Interchangeable Commodity Product**

99. A commodity-like product is one that is standardized across suppliers, allowing for a high degree of substitutability among different suppliers in the market. When products offered by different suppliers are viewed as interchangeable by purchasers, it is easier for the suppliers to agree on prices for the product in question and it is easier to monitor these prices effectively. By definition, generic drugs are interchangeable.

100. Generic drugs of the same chemical composition are effectively commodity products because the primary mechanism through which they compete is price. Because the FDA, when approving an ANDA, is required to determine whether a generic drug product is bioequivalent to the brand's NDA, an AB-rating permits a pharmacist to substitute an AB-rated generic for its branded counterpart, as well as to substitute one AB-rated generic for another AB-rated generic for the same branded product. (Depending on a given state's law, a pharmacist may also be able to substitute non-AB rated drugs, provided that certain conditions are met.)

101. Defendants' divalproex ER products are AB-rated generics of their branded version, enabling pharmacists to substitute them for the branded version automatically under their respective state's generic substitution laws.

102. Moreover, because generic manufacturers generally spend little effort advertising or detailing their generic compounds (*i.e.*, the practice of providing promotional materials and free samples to physicians), the primary means for one generic manufacturer to differentiate its product from another generic competitor's is through price reductions.<sup>41</sup> The need to compete on price can drive producers of commodity products to conspire – as they did here – to fix prices.

#### **4. The Generic Divalproex ER Market Is Highly Concentrated**

103. Companies that are not part of the conspiracy can erode conspirators' market shares by offering products at lower, more competitive prices. This reduces revenue and makes sustaining a conspiracy more difficult. A concentrated market is more susceptible to collusion and other anticompetitive practices.

104. In the market for divalproex ER, however, there is no realistic threat that a fringe of competitive sellers will take market share from Defendants. The divalproex ER market is highly concentrated and is dominated by a handful of companies: Mylan, Par, Dr. Reddy's, Impax, and Zydus. Defendants in the market for divalproex ER have oligopolistic power over the market, which enables them to raise prices without losing market share to non-conspirators and facilitated their ability to coordinate pricing for divalproex ER by monitor prices in the downstream market and police deviations from agreed upon prices. Moreover, the dramatic price increases since 2013 demonstrate that no Defendant is willing to meaningfully lower its prices to gain market share, as would be expected in a competitive marketplace.

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<sup>41</sup> See Congressional Budget Office, Promotional Spending for Prescription Drugs, Economic & Budget Issues Brief (Dec. 2, 2009), at 1.

105. As the dominant players in the divalproex ER market, Defendants were able to fix, raise, and maintain their prices for divalproex ER without competitive threats from rival generic drug manufacturers.

### **5. Manufacturers of Generic Divalproex ER Have Overlapping Products**

106. The dominant manufacturers of divalproex ER also make several other drug products and thus, have overlapping product portfolios with other non-divalproex producing generic manufacturers. This product overlap incentivizes these manufacturers to coordinate production and sales of these overlapping products. For example, many divalproex ER manufacturers also make digoxin and doxycycline, two drugs that are the subjects of both a DOJ criminal investigation and numerous civil class actions in *In re Generic Digoxin and Doxycycline Antitrust Litigation* now pending before Judge Cynthia Rufe in the District Court for the Eastern District of Pennsylvania, as well as other generic drugs:

Generic	Digoxin	Doxycycline	Divalproex ER	Pravastatin
<b>Dr. Reddy's</b>			✓	✓
<b>Impax</b>	✓	✓	✓	
<b>Mylan</b>	✓	✓	✓	✓
<b>Par</b>	✓	✓	✓	
<b>Zydus</b>			✓	✓

107. This product overlap provided these manufacturers with the opportunity and incentive to conspire to fix prices and allocate sales of these products.

### **6. Defendants' Pricing Actions Were Against Their Self-Interest**

108. Competitive firms in a competitive, commoditized marketplace will typically price their products aggressively, relative to their competitors' products. Firms price aggressively with the understanding that if they do not do so, other competitors undercut their



relatively high price, taking sales – and ultimately market share – away from the firms that are pricing less aggressively.

109. Here, however, Defendants failed to price aggressively relative to their competitors. Rather than attempt to take sales, revenue, and market share away from one another, Defendants instead sought to meet the price increases made by others and extract supracompetitive prices from Plaintiff and members of the Classes.

110. Such conduct was against Defendants' self-interest because rather than cut prices to gain sales, revenues, and market share, Defendants instead sought to sacrifice these potential gains in favor of cartel pricing. Defendants' failure to cut prices in the face of price increases from competitors suggests that Defendants were conspiring to fix and raise prices, rather than competing on price.

### **VIII. ANTITRUST IMPACT**

111. During the relevant period, Plaintiff and Class Members purchased substantial amounts of divalproex ER indirectly from Defendants. As a result of Defendants' illegal conduct, these purchasers have paid, and continue to pay, artificially inflated prices for divalproex ER. The prices paid were substantially higher than the prices that Plaintiff and Class Members would have paid absent the illegal conduct alleged in this Complaint.

112. As a consequence, purchasers of divalproex ER have sustained substantial losses and damage to their business and property in the form of overcharges – and their losses continue to date. The full amounts, forms, and components of such damages will be calculated after discovery and upon proof at trial.

113. Defendants' efforts to restrain competition in the divalproex ER market have substantially affected interstate commerce – and continue to do so.

114. At all material times, Defendants manufactured, promoted, distributed, and sold substantial amounts of divalproex ER in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Defendants' anticompetitive conduct had substantial intrastate effects in every state of purchase because, among other things, consumers and third-party payors within each state were forced to pay supracompetitive prices for divalproex ER.

115. At all times, Defendants transmitted funds and contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of divalproex ER.

116. Economists recognize that any overcharge at a higher level of distribution generally results in higher prices at every level below. Professor Herbert Hovenkamp explains that "[e]very person at every stage in the chain will be poorer" as a result of the anticompetitive price at the top.<sup>42</sup> He also says that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."<sup>43</sup>

117. The institutional structure of pricing and regulation in the pharmaceutical drug industry ensures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of divalproex ER to Plaintiff and Class Members.

118. Defendants' anticompetitive conduct enabled Defendants to charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent Defendants' unlawful actions.

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<sup>42</sup> See Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice*, at 564 (1994).

<sup>43</sup> *Id.*

119. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

120. The inflated prices that Plaintiff and Class Members have paid for divalproex ER, and continue to pay, are traceable to and the foreseeable result of, the overcharges caused by Defendants.

## **IX. CLASS ALLEGATIONS**

121. Plaintiff brings this action as a class action, under Fed. R. Civ. P. 23(a) and (b)(2), on behalf of themselves and a nationwide class of similarly situated individuals seeking injunctive and equitable relief:

### **The Injunctive Class:**

All persons or entities in the United States and its territories who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for divalproex ER, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as October 1, 2013 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased.

122. Plaintiff also brings this action as a class action, under Fed. R. Civ. P. 23(a) and (b)(3), on behalf of themselves and a class of similarly situated individuals seeking damages arising from Defendants' conduct as described below:

### **The Damages Class:**

All persons or entities who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for: divalproex ER, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as October 1, 2013 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased in Minnesota.

123. The following persons and entities are excluded from the above-described Classes:

- a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;
- b. All governmental entities, except for government-funded employee benefit plans;
- c. All persons or entities who purchased divalproex ER for purposes of resale or directly from Defendants or their affiliates;
- d. Fully-insured health plans (plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);
- e. Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs); and
- f. The judges in this case and any members of their immediate families.

124. Members of the Classes are so numerous that joinder is impracticable. Plaintiff believes that there are thousands of members of each class.

125. Plaintiff's claims are typical of the claims of the members of the Classes. Plaintiff and members of the Classes were damaged by the same wrongful conduct by Defendants in that they paid artificially inflated prices for divalproex ER as a result of Defendants' wrongful conduct – and continue to do so.

126. Plaintiff will fairly and adequately protect and represent the interests of the Classes. Plaintiff's interests are coincident with, and not antagonistic to, those of the members of the Classes.

127. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with experience in class action antitrust litigation involving pharmaceutical products.

128. Questions of law and fact common to the members of the Classes predominate over questions that may affect only individual members of the Classes because Defendants have acted on grounds generally applicable to each member of the Injunctive Class and Damages Class.

129. Questions of law and fact common to members of both Classes include:

- a. the identity of the participants in the conspiracy;
- b. whether Defendants conspired to fix, raise, maintain, and stabilize the prices of divalproex ER;
- c. whether Defendants conspired to allocate markets or customers with respect to divalproex ER;
- d. whether Defendants' conduct harmed competition in the divalproex ER market;
- e. whether Defendants' activities alleged herein have substantially affected interstate and intrastate commerce;
- f. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and members of the Classes in the nature of overcharges;
- g. the amount of overcharges paid by Plaintiff and members of the Classes in the aggregate; and
- h. the injunctive and other equitable relief needed to end Defendants' restraint and to restore competition in the divalproex ER market.

130. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated, geographically dispersed persons or entities to prosecute their common claims in a single forum

simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in management of this class action.

131. Plaintiff knows of no special difficulty to be encountered in this action that would preclude its maintenance as a class action.

## **X. CLAIMS FOR RELIEF**

### **A. First Claim for Relief**

#### **Violation of Sherman Act § 1, 15 U.S.C. § 1 (By Plaintiff and Injunctive Class Members Against All Defendants)**

132. Plaintiff incorporates the preceding paragraphs by reference.

133. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme to fix, raise, maintain, and stabilize the prices of divalproex ER, and allocate markets and customers for divalproex ER – and continue to do so.

134. Plaintiff and Injunctive Class Members would have paid substantially lower prices for divalproex ER if Defendants had competed instead of conspiring to restrain trade.

135. Defendants intended, and accomplished, a price-fixing conspiracy and horizontal market allocation for divalproex ER, which are *per se* violations of Section 1 of the Sherman Act. By their agreement, Defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act. As a result of this unreasonable restraint on competition, Plaintiff and Injunctive Class Members paid artificially inflated prices for divalproex ER – and continue to do so.

136. Plaintiff and Injunctive Class Members have suffered harm, and are continuing to suffer harm, as a result of paying higher prices for divalproex ER than they would have absent Defendants' anticompetitive conduct and continuing anticompetitive agreements. Plaintiff and Injunctive Class Members also face a continuing threat of injury from the unlawful conduct alleged in this Complaint.

137. Plaintiff and Injunctive Class Members have purchased substantial amounts of divalproex ER indirectly from Defendants.

138. Plaintiff and Injunctive Class Members seek a declaratory judgment pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a) that Defendants' conduct violates Section 1 of the Sherman Act.

139. Plaintiff and Injunctive Class Members also seek equitable and injunctive relief, including disgorgement of profits, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, and other relief to ensure that the same or similar anticompetitive conduct does not reoccur in the future.

**B. Second Claim for Relief**

**State Antitrust Violations  
(By Plaintiff and Damages Class Members Against All Defendants)**

140. Plaintiff incorporates the preceding paragraphs by reference.

141. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme to fix, raise, maintain, and stabilize the prices of divalproex ER and allocate markets and customers for divalproex ER – and continue to do so.

142. Defendants' unlawful conduct harmed Plaintiff and Damages Class Members in the manner explained above.

143. Defendants' unlawful conduct covered a sufficiently substantial percentage of the relevant market to harm competition.

144. Defendants' actions constitute horizontal market allocation and price-fixing agreements between actual and potential competitors and are illegal per se under state antitrust laws.

145. Defendants' supracompetitive pricing constitute a continuing violation of the laws of Minnesota in that each purchase by Plaintiff or a member of the Damages Class of supracompetitively priced divalproex ER caused injury to their business or property – and continue to do so.

146. Defendants have entered into an unlawful agreement in restraint of trade in violation of Minnesota Statutes §§ 325D.49, *et seq.* Defendants' combinations or conspiracies had the following effects: (1) divalproex ER price competition was restrained, suppressed, and eliminated throughout Minnesota; (2) divalproex ER prices were raised, fixed, maintained and stabilized at artificially high levels throughout Minnesota; (3) Plaintiff and members of the Damages Class were deprived of free and open competition; and (4) Plaintiff and members of the Damages Class paid supracompetitive, artificially inflated prices for divalproex ER. During the Class Period, Defendants' illegal conduct substantially affected Minnesota commerce. As a direct and proximate result of Defendants' unlawful conduct, Plaintiff and members of the Damages Class have been injured in their business and property and are threatened with further injury. By reason of the foregoing, Defendants have entered into agreements in restraint of trade in violation of Minnesota Statutes §§ 325D.49, *et seq.* Accordingly, Plaintiff and members of the Damages Class seek all relief available under Minnesota Statutes §§ 325D.49, *et seq.*



147. Plaintiff and Damages Class Members have been and continue to be injured in their business or property by Defendants' antitrust violations. Their injuries consist of: (1) being denied free and open competition between competitors in the markets for divalproex ER; and (2) paying higher prices for divalproex ER than they would have paid in the absence of Defendants' wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

148. Plaintiff and Damages Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

149. Defendants are jointly and severally liable for all damages suffered by Plaintiff and Damages Class Members.

150. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the above-listed state antitrust laws.

**C. Third Claim for Relief**

**Unjust Enrichment  
(By Plaintiff and Damages Class Members Against All Defendants)**

151. Plaintiff incorporates the preceding paragraphs by reference.

152. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

153. Defendants have benefited and continue to benefit from the overcharges on sales of divalproex ER made possible by the unlawful and inequitable acts alleged in this Complaint.

154. Defendants' financial benefits are traceable to Plaintiff's and Damages Class Members' overpayments for divalproex ER.

155. Plaintiff and Damages Class Members have conferred and continue to confer an economic benefit upon Defendants in the nature of profits resulting from unlawful overcharges, to the economic detriment of Plaintiff and Damages Class Members.

156. It would be futile for Plaintiff and Damages Class Members to seek a remedy from any party with whom they had or have privity of contract. Defendants have paid no consideration to anyone for any of the benefits they received indirectly from Plaintiff and Damages Class Members.

157. It would be futile for Plaintiff and Damages Class Members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased divalproex ER as those intermediaries are not liable and would not compensate Plaintiff and Damages Class Members for Defendants' unlawful conduct.

158. The economic benefit Defendants derived from charging monopolistic and artificially inflated prices for divalproex ER is a direct and proximate result of Defendants' unlawful practices.

159. The financial benefits Defendants derived rightfully belong to Plaintiff and Damages Class Members, who paid, and continue to pay, anticompetitive prices that inured to Defendants' benefit.

160. It would be inequitable under unjust enrichment principles under the laws of each of the states in the United States and the District of Columbia for Defendants to retain any of the overcharges Plaintiff and Damages Class Members paid for divalproex ER that were derived from Defendants' unfair and unconscionable methods, acts, and trade practices.

161. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiff and the Damages Class.

162. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiff and Damages Class Members.

163. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received that are traceable to Plaintiff and Damages Class Members.

164. Plaintiff and Damages Class Members have no adequate remedy at law.

## **XI. DEMAND FOR JUDGMENT**

Accordingly, Plaintiff, on its own behalf and on behalf of the proposed Classes, demands judgment that:

A. Determines that this case may be maintained as a class action pursuant to Federal Rule of Civil Procedure 23(a), (b)(2), and (b)(3), directs that reasonable notice of this case be given to members of the Classes under Rule 23(c)(2), and declares that Plaintiff is a proper representative of the Classes;

B. Declares that Defendants' conduct violated Section 1 of the Sherman Act, the other state statutes set forth above, and the common law of unjust enrichment;

C. Enjoins Defendants from continuing their illegal activities;

D. Enters judgment against Defendants joint and severally and in favor of Plaintiff and the Classes;

E. Grants Plaintiff and the Injunctive Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

F. Awards the Plaintiff and the Damages Class damages and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial, including interest;

G. Awards Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grants further relief as necessary to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, as the Court deems just.

## **XII. JURY DEMAND**

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed classes, demands a trial by jury on all issues so triable.

DATED: January 20, 2017

Respectfully Submitted,

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